Remarks

In this response, no amendments to the claims have been made. Applicants have presented arguments to overcome the Examiner's rejections.

Claim Rejections - 35 U.S.C. § 112 1st Enablement

The Examiner rejected Claims 1-15 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Examiner suggests that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants respectfully disagree with the Examiner.

The Federal Circuit has repeatedly stated that undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Wands,* 858 F.2d 731, 737 (Fed. Cir. 1988).

When an invention relates to a biochemical process such as gene modification, protein expression, and immune response, and success is not assured, that does not mean that generic inventions are thereby invalid. *Capon v. Eshhar,* 418 F.3d 1349, 1360 (Fed. Cir. 2005). *See also In re Angstadt,* 537 F.2d 498, 504 (C.C.P.A. 1976) (holding that the evidence as a whole, including the inoperative as well as the operative examples, negates the PTO position that persons of ordinary skill in this art, given its unpredictability, must engage in undue experimentation to determine which complexes work. The key word is "undue," not "experimentation").

Further, the burden is on the Examiner to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993). *See also* MPEP § 2164.04. In examining a patent application, the Examiner is required to assume that the specification complies with the enablement provision of § 112 unless it has acceptable evidence or reasoning to suggest otherwise. *In re Marzocchi*, 439 F.2d 220, 223 (C.C.P.A. 1971).

Applicants have human clinical data which demonstrates that administration of a GLP-1 compound to type 2 diabetic patients does not delay gastric emptying compared to placebo. Both Figures 1 and 2 show that the time to peak glucose concentration following

ingestion of a solid meal was identical for each group including the control group. Therefore, GLP-1 compounds may not delay gastric emptying and instead normalize gastric emptying such that patients no longer experience one or more of the symptoms associated with gastroparesis.

Thus, to shift the burden back to the Applicants, the Examiner must provide *evidence* why human clinical data showing that administration of GLP-1 compounds that result in normalizing gastric emptying would not be effective treatment for patients suffering from gastroparesis. Applicants respectfully request that the enablement rejection be withdrawn.

SUMMARY AND CONCLUSION

Applicants respectfully assert that the application is in condition for allowance. The claims are fully enabled.

If, for any reason, the Examiner feels that a telephone conversation would be helpful in expediting the prosecution of this case, the Examiner is urged to call me.

Respectfully submitted,

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